

USA Comments – TAHSC October 2006 Report

OIE Code Chapter on Bovine Spongiform Encephalopathy Chapter 2.3.13

Terrestrial Animal Health Standards Commission Report – October 2006

Suggested change:

Article 2.3.13.6.a

When importing from a country, zone or compartment posing a negligible BSE risk, Veterinary Administrations should require:

for cattle selected for export

the presentation of an international veterinary certificate attesting that the animals:

- a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.3;
- b) were born after the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants had been effectively enforced;

....

Article 2.3.13.12.

1. Ruminant derived meat and bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Article 2.3.13.3. should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants had been enforced;

Rationale: The United States recommends deleting (not adopting) the proposed language in Articles 2.3.13.6.a and 2.3.13.12. A sound technical justification for proposing this language is neither clear nor provided. For a country/zone/compartment to be recognized as negligible risk, that country/zone/compartment has to show that the BSE agent is not present in its domestic herd, or that any case was born more than 11 years ago, and that the feed ban has been effectively enforced for at least 8 years. It appears to be inconsistent that, on the one hand, restrictions are being reduced (e.g. removing limits on age and bone types) for the trade of bones for gelatine and collagen production even from

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countries with a “controlled” or “undetermined” risk, while on the other hand, restrictions are incremented (e.g. placing age requirements) for the trade of cattle and certain by-products from countries with a demonstrated “negligible” risk. Such language contradicts the scientific data upon which this chapter is based.

General Comment to proposed changes to Article 2.3.13.14 (re: Gelatin and Collagen):

The United States supports the removal of the requirement to exclude skulls and vertebrae from raw material used in the production of gelatin for zones posing a controlled or undetermined risk. We agree that such a decision is firmly grounded in science as demonstrated by the opinion of the scientific panel on biological hazards of the European Food Safety Authority (EFSA) wherein it is stated that the exclusion of skulls and vertebrae does not significantly contribute to the safety of gelatin.¹

That said, however, we believe that Article 2.3.13.14. should be deleted in its entirety and that ALL gelatin, irrespective of the raw material from which it is made, can be included in Article 2.3.13.1, commodities which can be traded without regard to the BSE risk status of the cattle population, as explained and documented below.

Suggested changes:

Article 2.3.13.1

...

1. When authorizing import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone, or compartment*:
 - a) *milk and milk products*;
 - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
 - c) hides and skins;
 - d) gelatine and ~~collagen~~ prepared ~~exclusively~~ from hides, ~~and~~ skins ~~or bones~~;
 - e) collagen prepared exclusively from hides and skins;
 - f) degreased bone chips and ossein (demineralised bone) utilized for gelatine production;
 - g) dicalcium phosphate obtained from the processing of ossein or bovine bone gelatine (with ~~no trace of protein or fat~~ less than 0.5% protein);
 - h) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a

¹ European Food Safety Authority Journal 2006 312 (1-28).

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stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

- i) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

Rationale (for the addition of gelatine prepared from bones):

The Terrestrial Code Commission received and considered “Supporting Documentation for Chapter 2.3.13 of the Terrestrial Animal Health Code on BSE.” This report referenced the opinion of the scientific panel on biological hazards of the EFSA which indicates that “. . . relative human exposures to BSE due to gelatin produced from bones including the skull and vertebral column sourced from cattle of any age are very low ($<10^{-5}$) and do not support the continuation of the restriction prohibiting the inclusion of skull and vertebral column.”²

However, this report states that the EFSA risk assessment did not consider the risk of sourcing bones from animals other than those deemed fit for human consumption and, therefore, those passing ante-mortem and post-mortem inspections. Further, this report indicates that to be consistent with the conservative approach adopted with respect to BSE, the commercial process for gelatin production must have been correctly carried out.

We believe these two restrictions are neither appropriate nor needed to ensure the safe supply of gelatin. Extensive research studies conducted by credible and independent scientists, and published in peer-reviewed research journals have demonstrated that the common process of manufacturing bovine gelatin provides significant assurance of gelatin safety. Specifically, studies have shown current minimum processes that all manufacturers have in common (and that technically must be utilized to produce a marketable product) are more than sufficient to eliminate BSE infectivity from “worst case” artificially contaminated raw materials. This “worst case” infectivity of $10^{8.4}$ is far more than that found in raw materials sourced in the country which had the highest incidence of BSE at the height of the BSE epidemic.^{3 4 5} Gelatin is a high-purity protein

² Appendix XXVIII of the report of the meeting of the OIE Terrestrial Animal Health Standards Commission 2-13 October 2006.

³ Grobbs AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatin. *Biotechnology and Applied Biochemistry*, 39; 329-338.

⁴ Grobbs AH, Steele PJ, Taylor DM, Somerville RA, Schreuder BEC (2005). Inactivation of the BSE agent by heat and pressure process for manufacturing gelatin. *Veterinary Record*, 157; 277-289.

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manufactured through various refining processes in which each step of processing is capable of significantly inactivating BSE infectivity.

The New Zealand Food Safety Authority has proven through carefully conducted risk assessments the safety of gelatin beyond reasonable doubt regardless of the BSE status of source countries.⁶ Given this document, the fact that BSE is very much in decline and certainly the epidemic is well under control, and that the Terrestrial Code Commission is grounded in basing all decisions on science-based information, the United States, therefore, requests that all gelatin should be freely traded regardless of the BSE risk status of the cattle population.

Rationale (for the addition of degreased bone chips and ossein):

Even with the inclusion of ALL gelatin in Article 2.3.13.1, commodities that can be traded without any BSE related conditions regardless of the BSE risk status of the cattle population international trade will still be impeded due to restrictions placed on the immediate commodity, degreased bone chips, used exclusively in the manufacture of gelatin.

Bone itself is free from BSE infectivity. The finding of infectivity in bone marrow, on one occasion, is now being questioned as a procedural error by OIE.⁷

Before bones can be used in the manufacture of gelatin, fat and other impurities must be removed by a process called “degreasing”. The bones are crushed to a size of less than 12 mm and then washed and degreased in a process that removes any residues of fat, marrow or other soft tissues.

Studies evaluating the effectiveness of the degreasing process for removing nervous tissue proteins from bones have demonstrated that degreasing eliminates 98% to 99% of

⁵ Grobden AH, Steele PH, Somerville RA, Taylor DM (2006). Inactivation of transmissible spongiform encephalopathy agents during the manufacture of dicalcium phosphate from bone. *Veterinary Record*, 158; 361-366.

⁶ NZFSA (2005). Official's Review of New Zealand's BSE Country-Categorisation Measure. New Zealand Food Safety Authority, Wellington and published in “prions in Humans and Animals, Ed. By Hornlimann, Beat/ Riesner, Detlv / Kretzschmar, Hans. De Gruyter Veriag, Berlin (ISBN 978-3-11-018275-0).

⁷ OIE Terrestrial Animal Health Standards Commission/October 2006, Appendix XXVIII.

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such proteins.⁸ It has been shown that the degreasing process alone reduces any BSE contamination of bone by a factor of approximately 10^2 .⁹

When degreased bone chips are used to manufacture gelatin, there is no direct exposure of BSE infectivity (even if such were present). Therefore, the United States requests that degreased bone chips used in the production of gelatin should be traded without any BSE related conditions regardless of the BSE risk status of the cattle population.

For ossein:

Before degreased bone chip material can be utilized to produce gelatin, it must have the minerals present, including calcium and phosphate, removed from it. This is accomplished by soaking the bone chip in hydrochloric acid (approximately 4%, <pH 1.5) for a period of at least 2 days. The resultant demineralized collagen is known as ossein. Ossein is the component which undergoes further processing and purification and becomes gelatin. Ossein is a commodity for which there is international trade demand.

Research by Grobбен et al. has proven that this hydrochloric acid treatment significantly reduces any BSE infectivity, if such might be present. This reduction is cumulative to that accomplished by the bone chip degreasing process.¹⁰

Ossein is used exclusively in the manufacture of gelatin. Therefore, there can be no direct exposure of BSE infectivity from ossein, even if in the unlikely circumstance that it were present. Based on these research findings, ossein can be traded without any BSE related conditions regardless of the BSE risk status of the cattle population.

d. Rationale (to amend trade conditions for dicalcium phosphate):

Considerable mineral content is recovered from the hydrochloric acid treatment of bone chip used in the production of gelatin. These recovered minerals are further purified, followed by precipitation and drying. The resultant product is dicalcium phosphate.

Raw materials for bone gelatin production originate from healthy slaughtered cattle found fit for human consumption following ante-mortem and post-mortem inspections. The

⁸ Manzke U, Schlaf G, Poethke R, Felgenhauer K, Mader M (1996). On the removal of nervous proteins from materials used for gelatine manufacturing during processing. *Pharmazeutische Industrie*, 58 (9); 837-841.

⁹ Pharmaceutical Research and Manufactures of America BSE Committee (1998). Assessment of the risk of bovine spongiform encephalopathy in pharmaceutical products. *BioPharm*, 11 (3); 18-30.

¹⁰ Grobбен AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatin. *Biotechnology and Applied Biochemistry*, 39; 329-338.

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same processing steps applied for the pre-treatment of bones used to produce bone gelatin are followed for pre-treatment of bones for the production of dicalcium phosphate.

Accordingly, studies which demonstrate the safety of gelatin resulting from the pre-treatment of bone during degreasing and acid demineralization¹¹ also indicate that a very safe dicalcium phosphate is yielded as a by product of the gelatin manufacturing process. Further, a significant reduction of TSE infectivity under experimental conditions has been demonstrated for dicalcium phosphate by a recent validation study.¹²

¹¹ Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39; 329-338.

¹² Grobber AH, Steele PJ, Somerville RA, Taylor DM (2006). Inactivation of transmissible spongiform encephalopathy agents during the manufacture of dicalcium phosphate from bone. *Veterinary Record*, 158; 361-366.